K071297

510(k) Summary

JUN 22 2007

Impax SE SigmaCom Client
(PACS Medical Imaging Display Workstation)

Common/Classification Name: Picture Archiving and communications system (PACS), 21 CFR 892.2050
Proprietary Name: Impax SE SigmaCom Client (PACS Medical Imaging Display Workstation)

Agfa HealthCare Corporation
10 South Academy Street
Greenville, SC 29602-9048

Contact: Tom Holbrook, Prepared: DATE
Telephone: (519) 746-6210 ext. 3297
Facsimile: (519) 746-3745

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's Impax SE SigmaCom Client (PACS Medical Imaging Display Workstation).

The predicate devices are Agfa's previous earlier workstations, the OT3000 (K050751), the Embrace (mammography) workstation (K040555) and the Web1000 remote access workstation (K053458). This new device includes most of the clinical functions of the predicate devices but was developed by Agfa HealthCare Enterprise Solutions, Lognes, France.

B. DEVICE DESCRIPTION

The new device is a multifunction PACS workstation for displaying and interpretation of medical images. It includes functions similar to the predicates. It can be used as a general radiography or orthopedic workstation. It displays "for presentation" (MG) mammography images. Image processing is handled by the mammography modalities. It can also display 3D images acquired from CT and MR modalities. It provides user teleradiology functionalities to share information and consult with remote users and can be used to perform quality control activities related to patient images and data.

The principles of operation and technological characteristics of the new and predicate devices are the same.

C. INTENDED USE

The IMPAX SE SigmaCom Client Workstations are intended to perform operations relating to the display, digital processing, review, transfer, storage, printing, measurements, teleradiology exchange of medical images and patient demographic information and to be integrated with separately cleared third party applications. They are intended for use by the physician to aid diagnosis and by medical professionals whenever they require access to medical images and patient demographic information.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's Impax SE SigmaCom Client (PACS Medical Imaging Display Workstation) has the same indications for use as the legally marketed predicate devices with the exception that it does not offer users access to electronic orthopedic device templates.

This indication difference does not modify the intended diagnostic effect: To assist users performing measurements common to the orthopedic specialty.

The new device has the same control methods and operating principles as the predicates. Descriptive characteristics and data provided in this submission are sufficiently precise to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same in the proposed and predicate devices. Both the new device and the predicates are software applications installed on standard computers.

F. TESTING

Agfa's Impax SE SigmaCom Client (PACS Medical Imaging Display Workstation) has been tested for conformance to specifications.

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 22 2007

Mr. Tom Holbrook
Quality Assurance & Regulatory Affairs Manager
Agfa Healthcare Corporation
10 South Academy Street
GREENVILLE SC 29601

Re: K071297
Trade/Device Name: Impax SE SigmaCom Client (PACS Medical Imaging Display Workstation)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 4, 2007
Received: May 9, 2007

Dear Mr. Holbrook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071297

Device Name: **Impax SE SigmaCom Client (PACS Medical Imaging Display Workstation)**

Indications for Use:

The system is indicated for the storage, reading, interpretation, clinical review, analysis, annotation, distribution, printing, editing and processing of digital images and data acquired from any DICOM device by healthcare professionals, including radiologists, physicians, technologists and clinicians.

- With the Teleradiology option it can be used to consult and share information with remote users.
- With the Mammography option it can be used for screening and diagnosis (with MG, "For presentation" images only) from FDA approved modalities in softcopy and printed formats.
- With the Orthopedic option it can be used to perform common orthopedic measurements of the hip, knee, spine (Coxometry, Gonometry, Lipman Cobb).
- With the Slice Imaging option it can be used to process basic 3D rendering: MIP, MPR or series synchronization.
- With the Quality Assurance option it can be used by PACS administrators or technologists to perform quality control activities related to patient images and data.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071297

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)